Secure and Responsible Drug Disposal Act of 2010

Reverse Distributor Meeting

July 16, 2015

The United States Department of Justice
Drug Enforcement Administration

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Liaison and Policy Section
Office of Diversion Control

Disposal 21 CFR § 1317

The Problem: Easy Access

Ultimate User

Ultimate user means as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household."

21 USC § 802(27)

Ultimate User Methods of Disposal Prior to Disposal Final Rule

Disposal in Trash (ONDCP method); or

Flushing (FDA opioids and select CSs)

National Take-back Event

Transfer to Law Enforcement (Police Station Receptacles or local Take-back events)

DEA

Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provides ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner

- Amendment authorizes DEA to inspect all collection facilities

21 USC §§ 822(f) and (g)

Secure and Responsible Drug Disposal Act of 2010

- Regulations did not limit the ways that ultimate users may dispose of pharmaceutical controlled substances—**they expanded them**.
- Any method of pharmaceutical disposal that was valid for *ultimate users* prior to these regulations continues to be valid.

➢ Participation is voluntary.

➢ **DEA may not require any person to establish or operate a disposal program.**

21 USC §§ 822(g)(2)

Secure and Responsible Drug Disposal Act of 2010

- Disposal rule eliminated existing 21 CFR 1307.12 and 1307.21

- New part 1317 contains the requirements on:
  - disposal procedures;
  - collection of pharmaceutical controlled substances from ultimate users;
  - return and recall; and
  - destruction of controlled substances

Law Enforcement

- Law Enforcement may continue to conduct take-back events.
- Any person may partner with Law Enforcement.
- Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.
- Authorized collection receptacles and inner liners “should” be used.

21 CFR §§ 1317.35 and 1317.65

Collection

Collection means to receive a controlled substance for the purpose of destruction from an:

- Ultimate user,
- Person lawfully entitled to dispose of an ultimate user decedent's property, or
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

21 USC §§ 822(g)(3) and (4)

21 CFR § 1300.01(b)

Authorized to Collection

- The following persons are authorized to collect from ultimate user and other non-registrants for destruction:
  - Any DEA registrant authorized pursuant to § 1317.40
  - Federal, State, tribal, or local law enforcement when in the course of official duties and pursuant to § 1317.35

Registrants authorized to collect:

- Manufacturers
- Distributors
- Reverse Distributors
- Narcotic Treatment Programs
- Hospitals/clinics with an on-site pharmacy
- Retail Pharmacies

Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.

21 CFR § 1317.40

Collection Receptacle Location

- Must be securely placed and maintained:
  - Inside **collector's registered location**
  - Inside law enforcement's physical location, or
  - **Inside an authorized LTCF**

Collection Receptacle Location

- Registered location – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
- LTCF – located in secure area regularly monitored by LTCF employees.
- Hospital/clinic – located in an area regularly monitored by employees---**not** in proximity of where emergency or urgent care is provided.
- NTP – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)

Collection Receptacle Inner Liner

- Waterproof, tamper-evident, and tear-resistant.
- Removable and sealable upon removal without emptying or touching contents.
- Contents shall not be viewable from the outside when sealed (i.e., can't be transparent).
- Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.).
- Outside of liner shall have permanent, unique ID number.

21 CFR § 1317.60(a)

Mail-Back Programs

Mail-Back Program

Requirements of mail-back program

- Only lawfully possessed schedules II-V controlled substances may be collected
- Controlled and non-controlled substances may be collected together

21 CFR § 1317.70 (b)

Mail-Back Program – Who is Authorized?

Any authorized collector that has and utilizes at its registered location **(on-site)** a method of destruction consistent with § 1317.90

21 CFR § 1317.70

Mail-Back Package Specifications

- Packages may be made available for sale or free of charge;
- Any person may partner with a collector or law enforcement to make packages available to the public;
- Nondescript and no markings that indicate it contains controlled substances;
- Water- and spill-proof, tamper-evident, tear-resistant, and sealable;
- Pre-addressed with the collector's registered address;
- Pre-paid postage;
- Unique ID number so package can be tracked; and
- Instructions for mailing.

21 CFR § 1317.70 (c)

Authorized Collector Physical Security

Non-Practitioner

Collected substances must be stored as a C-II

21 CFR § 1317.05(c)(1)(ii) and (c)(2)(ii)

Authorized Collector Personnel Security

- A Collector shall not employ, as an agent or employee who has access to or influence over controlled substances, any person who has:
  - A felony offense conviction related to controlled substances; or
  - Had a DEA application for registration denied, or had a DEA registration revoked, suspended, or surrendered for cause

21 CFR § 1301.71(f)

Registrant Disposal

Registrant Disposal - Inventory

Practitioner & Non-Practitioner may dispose of inventory:

- Prompt on-site destruction
- Prompt delivery to **reverse distributor** by common or contract carrier or reverse distributor pick-up
- Return and recall : Prompt delivery by common or contract carrier or pick-up at the registered location

Practitioner may also request assistance from the SAC

Non-practitioner may also transport by its own means

21 CFR § 1317.05(a) and (b)

Reverse Distribution

Reverse Distribution

Reverse distribute means to acquire controlled substances from another registrant or law enforcement for the purpose of return or destruction.

Reverse distributor is a person registered with the Administration as a reverse distributor

21 CFR § 1300.01(b)

Registrants that reverse distribute:

- Shall destroy controlled substances received for purpose of destruction no later than 30 calendar days of receipt
- Day 1 is the day the substances are physically acquired through pick-up or delivery

21 CFR §§ 1317.15(d) and 1317.55(c)(2)

Reverse Distributor

- Any person that reverse distributes a controlled substance shall be registered with DEA as a reverse distributor unless exempted by law or authorized pursuant to this chapter.

  – *21 CFR § 1317.05(c)(2)(iv) & (v)* - Distributors are authorized to *reverse distribute* sealed inner liners from authorized collectors

21 CFR § 1317.05(a)

Reverse Distributor - Acquisition

A reverse distributor shall acquire controlled substances from a registrant in the following manner:

- Pick-up at the registrant's registered location or authorized collection site; or
- Receive controlled substances delivered by common or contract carrier or delivered directly by a non-practitioner registrant.
  - If delivered, delivery shall be made to the registered location of the person who reverse distributes. (Once en route, the delivery may not be re-routed.)
  - All deliveries shall be personally received by an employee at the registered location.

21 CFR §§ 1317.15(b) and 1317.55

Reverse Distribute - Procedure

Upon acquisition of a controlled substance by delivery or pick-up, the authorized entity receiving shall:

- Immediately store at registered location or immediately transfer to registered location for secure storage until timely destruction or prompt return;
- Promptly deliver to the manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf, or
- Timely destroy

Destruction must occur **no later than 30 calendar days** after receipt.

21 CFR §§ 1317.15(c) and (d); and 21 CFR § 1317.55

Reverse Distributor Personnel Security

A reverse distributor shall not employ, as an agent or employee who has access to or influence over controlled substances, any person who has:

- A felony offense conviction related to controlled substances; or
- Had a DEA application for registration denied, or had a DEA registration revoked, suspended, or surrendered for cause

21 CFR § 1301.74(m)

Reverse Distribution Records

- Controlled substances acquired for return or recall:
  - The date of receipt; the name and quantity of each controlled substance received; the name, address, and DEA number of the person from whom the substance was received; and the reason for return, and
  - The date of return; the name and quantity of each controlled substance returned; the name, address, and DEA number of the person from whom the substance was received; the name, address, and DEA number to whom the substance was returned; and the method of return.

21 CFR § 1304.22(e)(1)

Reverse Distribution Records

- Controlled substances acquired from registrant inventory for purposes of destruction:
  - The date of receipt; name and quantity of each controlled substance received; and name, address, and DEA number of the person from whom the substance was received; and
  - The date, place, and method of destruction; name and quantity of each controlled substance destroyed; name, address, and DEA number of the person from whom the substance was received; and names and signatures of the 2 employees of the registrant that witnessed the destruction.

21 CFR § 1304.22(e)(2)

Reverse Distribution Records

- Total quantity shall be recorded as:
  - Bulk form: to the nearest metric unit weight or volume consistent with unit size
  - Finished form: each finished form, number of units or volume of finished form in each commercial container, and number of commercial containers
  - Commercial containers with broken seals:
    - Exact count or measure of the contents (schedule II); or
    - Estimated count or measure of the contents (schedules III-V); or
    - Exact count (containers holding more than 1,000 units).

21 CFR § 1304.22(e)(3)

Reverse Distribution Records

- Sealed inner liners and mail-back packages acquired from collectors or law enforcement:
  - Date acquired, number acquired, size (inner liners), unique ID number, and the name, address and, for registrants, the DEA number of the person from whom received.
  - Date, place, and method of destruction; the number destroyed; unique ID number, and the names and signatures of the 2 employees who witnessed the destruction.

21 CFR § 1304.22(e)(4)

Reverse Distribution Records

- For all records, the record of receipt shall be maintained together with the corresponding DEA Form 41.

21 CFR § 1304.22(e)(5)

Requirements for Destruction of Controlled Substances

Destruction of Controlled Substances

- All controlled substances destroyed by a registrant or caused to be destroyed by a registrant shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered non-retrievable.

21 CFR § 1317.90

Destruction of Controlled Substances

Non-retrievable means the condition or state to which a controlled substance shall be rendered following a process that permanently alters the substance's physical or chemical condition or state through irreversible means, and thereby renders the controlled substance unavailable and unusable for all practical purposes.

21 CFR § 1300.05

Destruction of Controlled Substances

- Destruction shall be in accordance with the following requirements:
  - Transfer to registrant or person authorized to accept for destruction
  - Transport to a registered location
  - Transport to a non-registered location for destruction
  - On-site destruction

21 CFR § 1317.95

Destruction of Controlled Substances

- Transfer and transport for destruction
  - Transportation directly to registered location or destruction location
  - 2 employees accompany the controlled substances to location
  - 2 employees load & unload or observe load & unload until transfer is complete

21 CFR § 1317.95(b) and (c)

Destruction Procedures

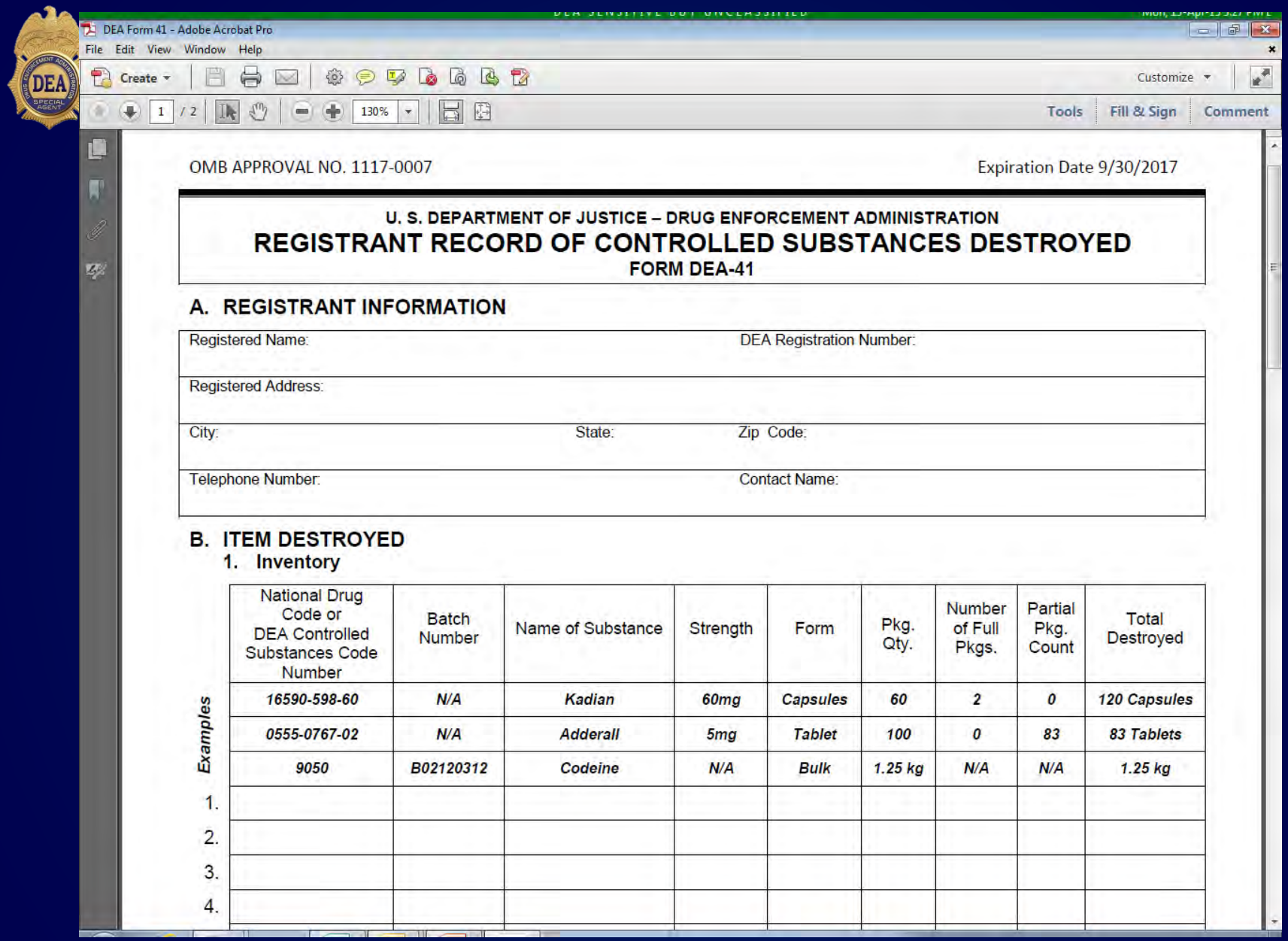
- 2 employees of the registrant shall handle or observe the handling of any controlled substance until it is rendered non-retrievable, and
- 2 employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

21 CFR § 1317.95(c) and (d)

DEA Form 41

- Form 41 shall be used to record the **destruction of all controlled substances, including controlled substances acquired from collectors.**
  - The Form 41 shall include the names and signatures of the two employees who witnessed the destruction.
  - Exceptions for DEA Form 41:
    - Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41
    - Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41

21 CFR § 1304.21(e)



OMB APPROVAL NO. 1117-0007 Expiration Date 9/30/2017

U. S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION

REGISTRANT RECORD OF CONTROLLED SUBSTANCES DESTROYED

FORM DEA-41

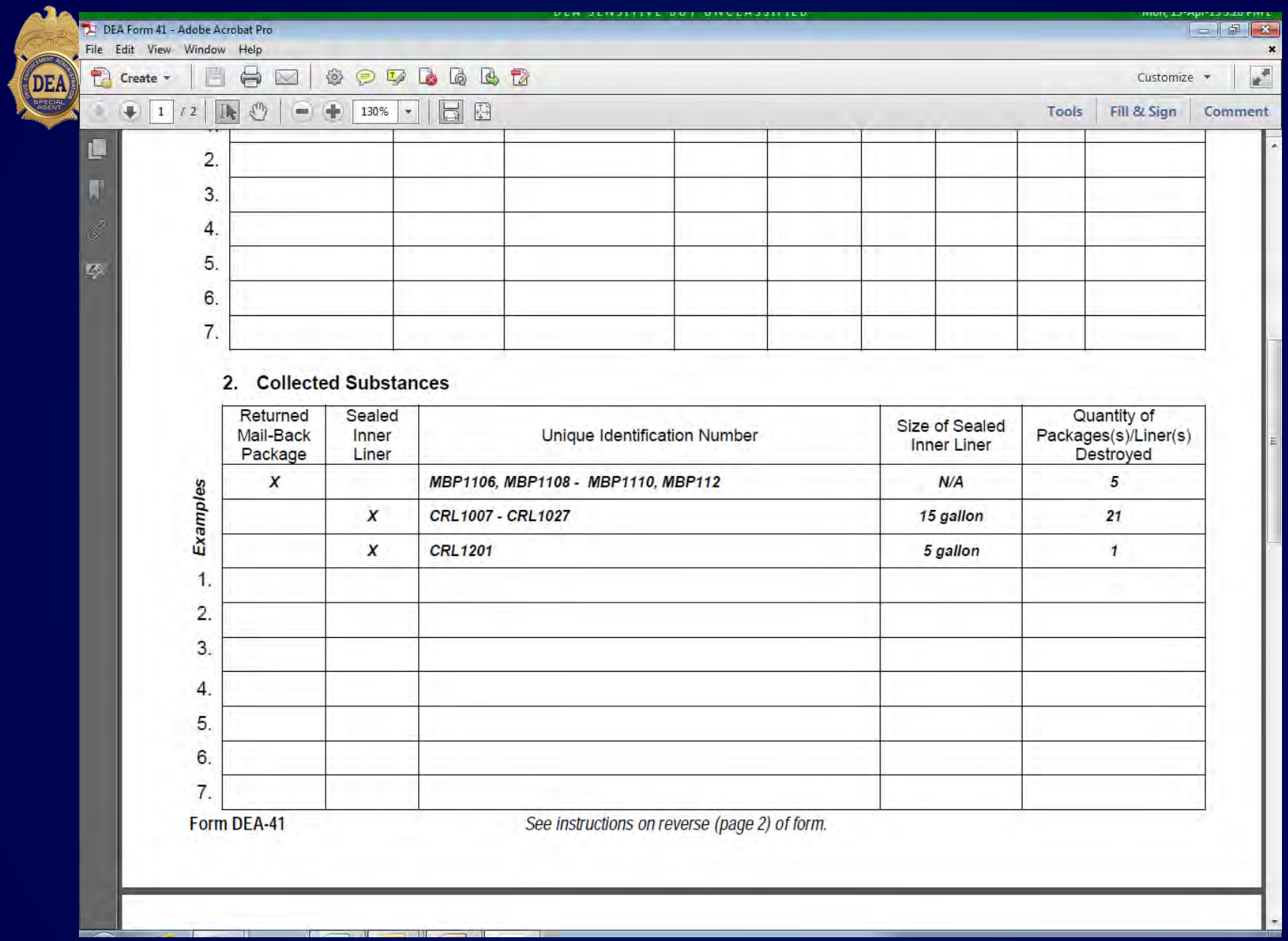
A. REGISTRANT INFORMATION

Registered Name:		DEA Registration Number:
Registered Address:		
City:	State:	Zip Code:
Telephone Number:		Contact Name:

B. ITEM DESTROYED

1. Inventory

	National Drug Code or DEA Controlled Substances Code Number	Batch Number	Name of Substance	Strength	Form	Pkg. Qty.	Number of Full Pkgs.	Partial Pkg. Count	Total Destroyed
Examples	*16590-598-60*	*N/A*	*Kadian*	*60mg*	*Capsules*	*60*	*2*	*0*	*120 Capsules*
	0555-0767-02	*N/A*	*Adderall*	*5mg*	*Tablet*	*100*	*0*	*83*	*83 Tablets*
	9050	*B02120312*	*Codeine*	*N/A*	*Bulk*	*1.25 kg*	*N/A*	*N/A*	*1.25 kg*
1.									
2.									
3.									
4.									


DEA Form 41 - Adobe Acrobat Pro

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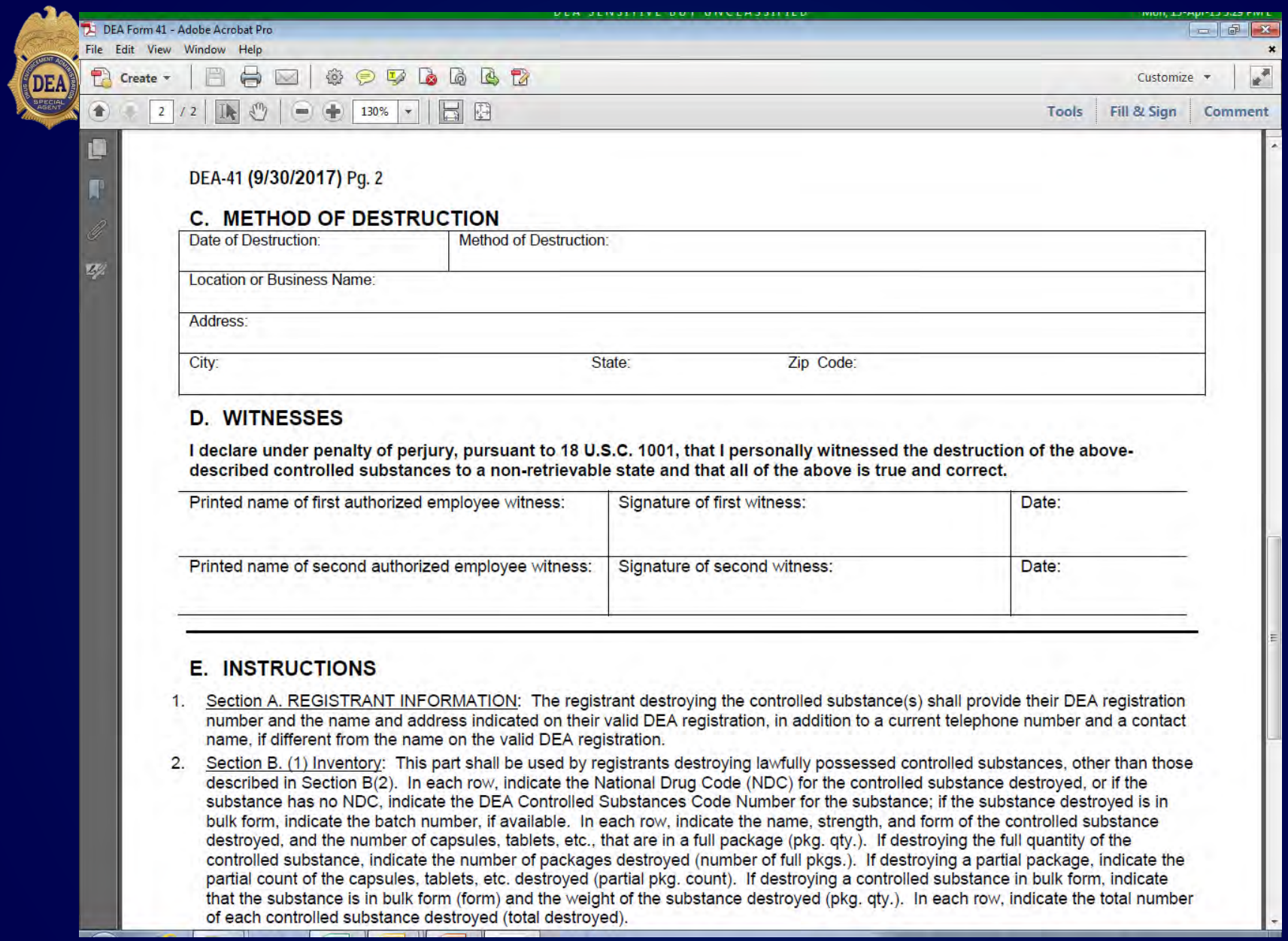
2.									
3.									
4.									
5.									
6.									
7.									

2. Collected Substances

	Returned Mail-Back Package	Sealed Inner Liner	Unique Identification Number	Size of Sealed Inner Liner	Quantity of Packages(s)/Liner(s) Destroyed
Examples	*X*		*MBP1106, MBP1108 - MBP1110, MBP112*	*N/A*	*5*
		X	*CRL1007 - CRL1027*	*15 gallon*	*21*
		X	*CRL1201*	*5 gallon*	*1*
1.					
2.					
3.					
4.					
5.					
6.					
7.					

Form DEA-41 *See instructions on reverse (page 2) of form.*



DEA-41 **(9/30/2017)** Pg. 2

C. METHOD OF DESTRUCTION

Date of Destruction:	Method of Destruction:	
Location or Business Name:		
Address:		
City:	State:	Zip Code:

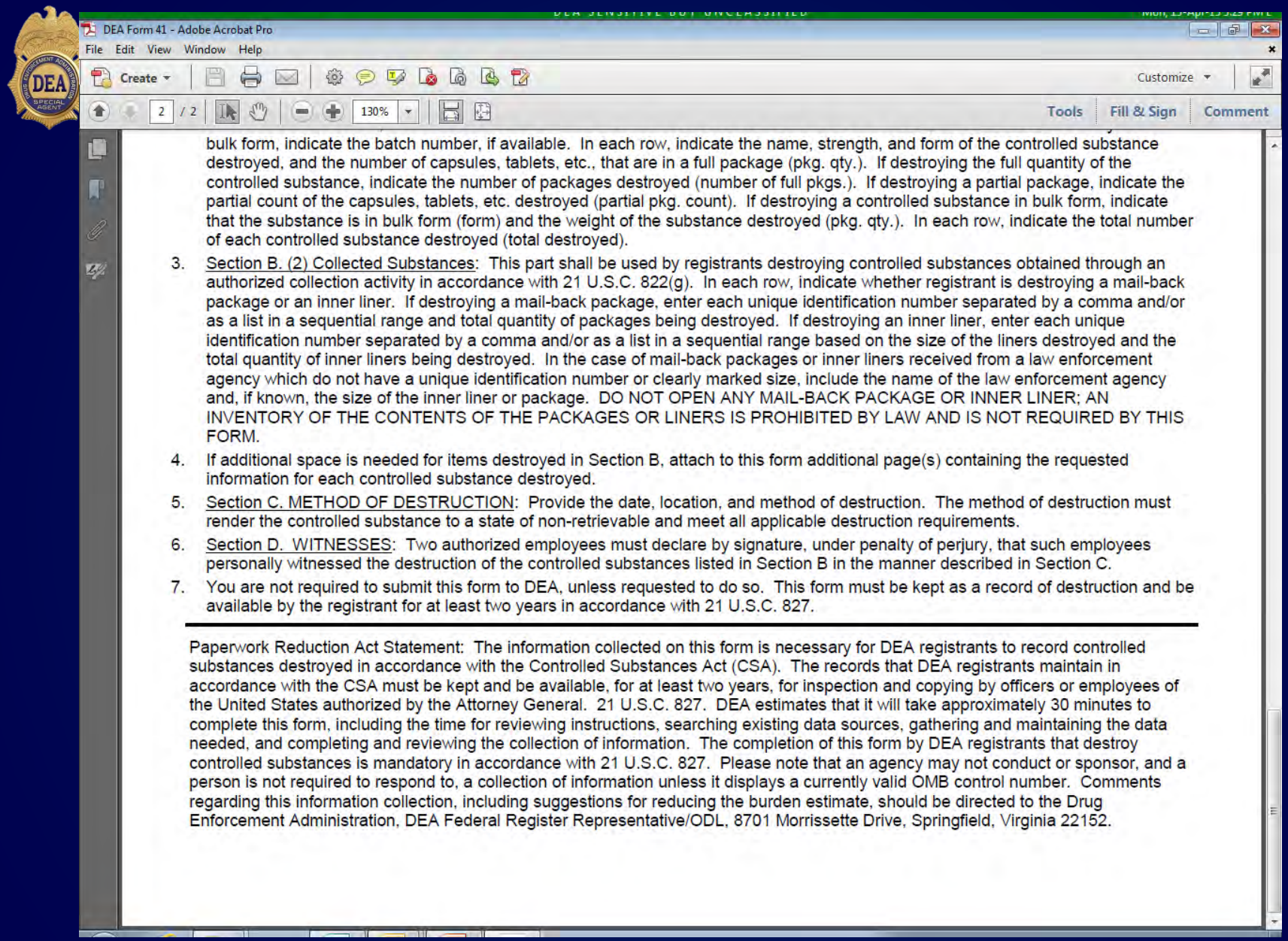
D. WITNESSES

I declare under penalty of perjury, pursuant to 18 U.S.C. 1001, that I personally witnessed the destruction of the above-described controlled substances to a non-retrievable state and that all of the above is true and correct.

Printed name of first authorized employee witness:	Signature of first witness:	Date:
Printed name of second authorized employee witness:	Signature of second witness:	Date:

E. INSTRUCTIONS

1. Section A. REGISTRANT INFORMATION: The registrant destroying the controlled substance(s) shall provide their DEA registration number and the name and address indicated on their valid DEA registration, in addition to a current telephone number and a contact name, if different from the name on the valid DEA registration.
2. Section B. (1) Inventory: This part shall be used by registrants destroying lawfully possessed controlled substances, other than those described in Section B(2). In each row, indicate the National Drug Code (NDC) for the controlled substance destroyed, or if the substance has no NDC, indicate the DEA Controlled Substances Code Number for the substance; if the substance destroyed is in bulk form, indicate the batch number, if available. In each row, indicate the name, strength, and form of the controlled substance destroyed, and the number of capsules, tablets, etc., that are in a full package (pkg. qty.). If destroying the full quantity of the controlled substance, indicate the number of packages destroyed (number of full pkgs.). If destroying a partial package, indicate the partial count of the capsules, tablets, etc. destroyed (partial pkg. count). If destroying a controlled substance in bulk form, indicate that the substance is in bulk form (form) and the weight of the substance destroyed (pkg. qty.). In each row, indicate the total number of each controlled substance destroyed (total destroyed).



bulk form, indicate the batch number, if available. In each row, indicate the name, strength, and form of the controlled substance destroyed, and the number of capsules, tablets, etc., that are in a full package (pkg. qty.). If destroying the full quantity of the controlled substance, indicate the number of packages destroyed (number of full pkgs.). If destroying a partial package, indicate the partial count of the capsules, tablets, etc. destroyed (partial pkg. count). If destroying a controlled substance in bulk form, indicate that the substance is in bulk form (form) and the weight of the substance destroyed (pkg. qty.). In each row, indicate the total number of each controlled substance destroyed (total destroyed).

3. Section B. (2) Collected Substances: This part shall be used by registrants destroying controlled substances obtained through an authorized collection activity in accordance with 21 U.S.C. 822(g). In each row, indicate whether registrant is destroying a mail-back package or an inner liner. If destroying a mail-back package, enter each unique identification number separated by a comma and/or as a list in a sequential range and total quantity of packages being destroyed. If destroying an inner liner, enter each unique identification number separated by a comma and/or as a list in a sequential range based on the size of the liners destroyed and the total quantity of inner liners being destroyed. In the case of mail-back packages or inner liners received from a law enforcement agency which do not have a unique identification number or clearly marked size, include the name of the law enforcement agency and, if known, the size of the inner liner or package. DO NOT OPEN ANY MAIL-BACK PACKAGE OR INNER LINER; AN INVENTORY OF THE CONTENTS OF THE PACKAGES OR LINERS IS PROHIBITED BY LAW AND IS NOT REQUIRED BY THIS FORM.
4. If additional space is needed for items destroyed in Section B, attach to this form additional page(s) containing the requested information for each controlled substance destroyed.
5. Section C. METHOD OF DESTRUCTION: Provide the date, location, and method of destruction. The method of destruction must render the controlled substance to a state of non-retrievable and meet all applicable destruction requirements.
6. Section D. WITNESSES: Two authorized employees must declare by signature, under penalty of perjury, that such employees personally witnessed the destruction of the controlled substances listed in Section B in the manner described in Section C.
7. You are not required to submit this form to DEA, unless requested to do so. This form must be kept as a record of destruction and be available by the registrant for at least two years in accordance with 21 U.S.C. 827.

Paperwork Reduction Act Statement: The information collected on this form is necessary for DEA registrants to record controlled substances destroyed in accordance with the Controlled Substances Act (CSA). The records that DEA registrants maintain in accordance with the CSA must be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General. 21 U.S.C. 827. DEA estimates that it will take approximately 30 minutes to complete this form, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The completion of this form by DEA registrants that destroy controlled substances is mandatory in accordance with 21 U.S.C. 827. Please note that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Comments regarding this information collection, including suggestions for reducing the burden estimate, should be directed to the Drug Enforcement Administration, DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.

Reports Required by 21 CFR

deadiversion.usdoj.gov/21cfr_reports/surrend/index.html#instruct

Apps | Employee Personal Pa... | DEA Diversion Control ... | ROCIS Login Page | Playlist | Search | yo s... | Search Job Vacancies | The Alliance of States ...

INSTRUCTIONS
Registrant Record of Controlled Substances Destroyed - DEA Form 41

It is recommended that registrants review **21 CFR §1317 — Disposal**

1. **Section A. REGISTRANT INFORMATION:**
   The registrant destroying the controlled substance(s) shall provide their DEA registration number and the name and address indicated on their valid DEA registration, in addition to a current telephone number and a contact name, if different from the name on the valid DEA registration.
2. **Section B. (1) Inventory:**
   This part shall be used by registrants destroying lawfully possessed controlled substances, other than those described in Section B(2). In each row, indicate the National Drug Code (NDC) for the controlled substance destroyed, or if the substance has no NDC, indicate the DEA Controlled Substances Code Number for the substance; if the substance destroyed is in bulk form, indicate the batch number, if available. In each row, indicate the name, strength, and form of the controlled substance destroyed, and the number of capsules, tablets, etc., that are in a full package (pkg. qty.). If destroying the full quantity of the controlled substance, indicate the number of packages destroyed (number of full pkgs.). If destroying a partial package, indicate the partial count of the capsules, tablets, etc. destroyed (partial pkg. count). If destroying a controlled substance in bulk form, indicate that the substance is in bulk form (form) and the weight of the substance destroyed (pkg. qty.). In each row, indicate the total number of each controlled substance destroyed (total destroyed).
3. **Section B. (2) Collected Substances:**
   This part shall be used by registrants destroying controlled substances obtained through an authorized collection activity in accordance with **21 U.S.C. 822**(g). In each row, indicate whether registrant is destroying a mail-back package or an inner liner. If destroying a mail-back package, enter each unique identification number separated by a comma and/or as a list in a sequential range and total quantity of packages being destroyed. If destroying an inner liner, enter each unique identification number separated by a comma and/or as a list in a sequential range based on the size of the liners destroyed and the total quantity of inner liners being destroyed. In the case of mail-back packages or inner liners received from a law enforcement agency which do not have a unique identification number or clearly marked size, include the name of the law enforcement agency and, if known, the size of the inner liner or package. DO NOT OPEN ANY MAIL-BACK PACKAGE OR INNER LINER; AN INVENTORY OF THE CONTENTS OF THE PACKAGES OR LINERS IS PROHIBITED BY LAW AND IS NOT REQUIRED BY THIS FORM.
4. If additional space is needed for items destroyed in Section B, attach to this form additional page(s) containing the requested information for each controlled substance destroyed.
5. **Section C. METHOD OF DESTRUCTION:**
   Provide the date, location, and method of destruction. The method of destruction must render the controlled substance to a state of non-retrievable and meet all applicable destruction requirements.
6. **Section D. WITNESSES:**
   Two authorized employees must declare by signature, under penalty of perjury, that such employees personally witnessed the destruction of the controlled substances listed in Section B in the manner described in Section C.
7. You are not required to submit this form to DEA, unless requested to do so. This form must be kept as a record of destruction and be available by the registrant for at least two years in accordance with **21 U.S.C. 827**.

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General Recordkeeping

- Every registrant required to keep records shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package
- Separate records shall be maintained for each independent activity.
- Collection is an independent activity.

21 CFR § 1304.21(a) and (c)

ARCOS Exceptions/Exemptions

- Registrants that acquire recalled controlled substances may report as a single transaction.

21 CFR § 1304.33(f)(2)

- Collectors are exempt from ARCOS reporting only with respect to collected substances
- Reverse distributors and distributors that acquire controlled substances from collectors and law enforcement are exempt from ARCOS reporting only with respect to those collected substances.

21 CFR § 1304.33(g)(1) and (2)

DEA Form 222

- Exceptions to DEA 222 Order Forms:

- deliveries by ultimate user or other authorized person to an authorized DEA registrant for disposal
- distributions to reverse distributors and distributors by collectors and law enforcement
- deliveries by ultimate users for the purpose of recalls

– *21 CFR § 1305.03(e)–(g)*

DEA Form 106

DEA SENSITIVE BUT UNCLASSIFIED

DEA Form 106 - Adobe Acrobat Pro

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REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration. Complete page 1, and either page 2 or 3. Make two additional copies of the completed form. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL
No. 1117-0001
(Expiration Date 9/30/2017)

1. Name and Address of Registrant (include ZIP Code)

2. Phone No. (Include Area Code)

3. DEA Registration Number

4. Date of Theft or Loss

5. Principal Business of Registrant (Check one)
- 1 ☐ Pharmacy
- 2 ☐ Practitioner
- 3 ☐ Manufacturer
- 4 ☐ Hospital/Clinic
- 5 ☐ Distributor
- 6 ☐ Methadone Program
- 7 ☐ Other (Specify) _____

6. County in which Registrant is Located

7. Was Theft reported to Police?
☐ Yes ☐ No

8. Name and Telephone Number of Police Department (Include Area Code)

9. Number of Thefts or Losses Registrant has Experienced in the Past 24 Months

10. Type of Theft or Loss (Check one and complete items below as appropriate)
- 1 ☐ Night Break-in
- 2 ☐ Armed Robbery
- 3 ☐ Employee Pilferage
- 4 ☐ Customer Theft
- 5 ☐ Other (Explain)
- 6 ☐ Lost in Transit (Complete Item 14)

11. If Armed Robbery, was Anyone:
Killed? ☐ No ☐ Yes (How Many) _____
Injured? ☐ No ☐ Yes (How Many) _____

12. Purchase value to Registrant of Controlled Substances taken?
$

13. Were any pharmaceuticals or merchandise taken?
☐ No ☐ Yes (Est. Value)
$

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier

B. Name of Consignee

C. Consignee's DEA Registration Number

DEA SENSITIVE BUT UNCLASSIFIED

DEA Form 106 - Adobe Acrobat Pro
File Edit View Window Help
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Customize
Tools Fill & Sign Comment

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier	B. Name of Consignee	C. Consignee's DEA Registration Number

D. Was the carton received by the customer?	E. If received, did it appear to be tampered with?	F. Have you experienced losses in transit from this same carrier in the past?
☐ Yes ☐ No	☐ Yes ☐ No	☐ No ☐ Yes (How Many) _____

15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?

16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.

17. What security measures have been taken to prevent future thefts or losses?

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Report theft or loss of Controlled Substances.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

In accordance with the Paperwork Reduction act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The Valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

FORM DEA-106 Previous editions obsolete

CONTINUE ON REVERSE

DEA SENSITIVE BUT UNCLASSIFIED

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LIST OF CONTROLLED SUBSTANCES LOST OR STOLEN

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
Examples	Desoxyn	00074-3377-01	Methamphetamine Hydrochloride	5 mg	Tablets	300
	Demerol	00409-1181-30	Meperidine Hydrochloride	50 mg/ml	Vial	150 ml
	Robitussin A-C	00031-8674-25	Codeine Phosphate	2 mg/cc	Liquid	5676 ml
1.						
2.						
3.						
4.						
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17.						
18.						
19.						
20.						

Remarks: (Optional)

Express Quantity in Dosage Units, or Milliliters for Liquids

I certify that the foregoing information is correct to the best of my knowledge and belief.

Sign and Print Name _____ Title _____ Date _____

DEA SENSITIVE DOJ UNCLASSIFIED

LIST OF MAIL-BACK PACKAGES OR INNER LINERS LOST OR STOLEN

	Mail-Back Package	Inner Liner	Unique Identification Number(s)	Size of Inner Liner	Total Quantity Lost or Stolen
Examples	X		MBP1106, MBP1108 – MBP1110, MBP1112	N/A	5
		X	CRL1007 – CRL1027	15 GALLON	21
		X	CRL1201	5 GALLON	1
1.					
2					
3.					
4.					
5.					
6.					
7.					
8.					

Remarks: (Optional)

Express in Total Quantities

If you are an authorized Retail Pharmacy or Hospital/Clinic with an onsite Pharmacy and reporting a theft or loss at a Long-Term Care Facility (LTCF), provide name and address of LTCF.

Name of LTCF

Address, City, State, Zip Code

I certify that the foregoing information is correct to the best of my knowledge and belief.

Sign and Print Name

Title

Date

Freight Forwarding Facilities

Freight Forwarding Facilities

- Definition changed to specifically ***exclude*** *reverse distributors* from being able to use a freight forwarding facility.

21 CFR § 1300.01(b)

- Freight forwarding facilities cannot be used to transfer sealed inner liners and their contents.

21 CFR § 1317

- Freight forwarding facilities can be used for registrant return or recall if: advance notice is provided and delivery is direct.

21 CFR § 1317.10(c)

Thank You

odlp@usdoj.gov